



## 510(k) Summary

**ArthroCare<sup>®</sup> Corporation**  
MultiFIX<sup>®</sup> S Knotless Fixation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

### General Information

Submitter Name: ArthroCare Corporation  
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Date Prepared: August 16, 2013

SEP 17 2013

### Device Name

Proprietary Name: MultiFIX<sup>®</sup> S Knotless Fixation System  
Common Name: Bone Anchor  
Classification Name: Smooth or threaded metallic bone fixation fastener  
Device Class: Class II  
Product Code: MBI  
CFR Section: 21 CFR 888.3040

### Predicate Device

MultiFIX<sup>®</sup> S Knotless Fixation System: K131182 (cleared July 29, 2013)

### Description

The MultiFIX S Knotless Fixation System (MultiFIX S) is an implantable bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. The MultiFIX S is a knotless fixation device, meaning that manually tying surgical knots is not necessary for the fixation of suture to tissue.

The MultiFIX S consists of two primary parts: an implantable bone anchor and an anchor inserter, which is preloaded with the anchor. The anchor inserter is a disposable tool.

The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by irradiation. Both the anchor and inserter are designed for single use only.

The MultiFIX S Knotless Fixation System consists of the bone anchor and associated instruments for implanting the bone anchor. In accordance with the ArthroCare Product Development Process, testing was performed to demonstrate the proposed device is substantially equivalent to the predicate device.

#### **Intended Use/Indications For Use**

The MultiFIX S Knotless Fixation Device is indicated for use in fixation of soft tissue to bone.

Examples of such procedures include:

**Shoulder:** Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair

**Ankle:** Lateral instability, medial instability, Achilles tendon repair/reconstruction, and midfoot reconstruction

**Foot:** Hallux valgus reconstruction

**Elbow:** Tennis elbow repair, biceps tendon reattachment

**Knee:** Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

#### **Non-Clinical Data**

Bench testing was performed on both the proposed and predicate devices. The test results demonstrate that the MultiFIX S meets its design, performance, and safety specifications. Based on the test results, the proposed device performs as intended and mechanical properties are substantially equivalent to the predicate devices when used in accordance with labeling.

#### **Clinical Data**

No clinical or animal data are included in this submission.

#### **Summary**

All testing demonstrates that the MultiFIX S performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are comparable to the predicate device, the MultiFIX S Knotless Fixation System is substantially equivalent. The minor differences between the proposed MultiFIX S and predicate device do not raise any new questions of safety or effectiveness.

<b>Comparison of Technological Characteristics</b>		
<b>Characteristics</b>	<b>Predicate Device MultiFIX S (K131182)</b>	<b>Proposed Device MultiFIX S</b>
Intended Use	Fixation of soft tissue to bone	Same
Delivery Method	Arthroscopic and Limited Access	Same
How Supplied	Sterile	Same
Suture Material	No. 2 UHMWPE Suture	Same
Anchor Material	Invisio PEEK Optima®	Same
Design Technology	Pound in Anchor with screw	Same
Bone Locking Mechanism	Interference Fit (threaded screw)	Same
Suture Locking Mechanism	Plug/Cylinder Compression	Same
# of Suture Legs	2, 3 or 4	Same
Diameter of Cortical Lock	5.5 mm & 6.5 mm	Same
Anchor Deployed Length	20 to 23 mm	Same
Device Length	299mm	291mm
Sterilization Method	Irradiation	Same
Packaging	Sterile / Thermoform Tray with Tyvek Lid	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

ArthroCare Corporation  
Mr. Mitchell Dhority  
Vice President, Regulatory Affairs  
7000 West William Cannon Drive  
Austin, Texas 78735

September 17, 2013

Re: K132590

Trade/Device Name: MultiFIX® S Knotless Fixation System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: August 16, 2013  
Received: August 19, 2013

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Mitchell Dhority

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 132590

Device Name: MultiFIX® S Knotless Fixation System

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE IF NEEDED)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.  
Division of Orthopedic Devices